

Effectiveness, acceptance and feasibility of *home-based intervention model* for tuberculosis contact tracing in Kashmir

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ABSTRACT

Background: As long as one case of tuberculosis is replaced by another, elimination of tuberculosis cannot be achieved. Contact tracing is an important strategy for detection of more TB cases early. The present study is concerned with an innovative method of contact tracing.

Methods: A quasi randomized interventional study was conducted in two TB Units of Kashmir for evaluation of newly designed interventional model for its effectiveness, acceptance and feasibility. Data was collected from 1st Jan 2014 to 30th June 2015.

Results: In interventional group of 598 eligible household contacts, total 27 (4.51%) contacts were detected as suffering from active pulmonary TB cases. Out these, 21 (3.51%) cases were diagnosed during initial home visit and 6 (1.04%) cases were diagnosed at 6th monthly follow up visit. In controlled group 593 eligible household contacts, total 7 (1.18%) contacts were found suffering from active pulmonary —TB during routine practice under RNTCP for contact screening. In interventional group, during initial home visit by the investigator, 423 (70.74%) of household contacts participated for study and during follow up visit at 6th month, 356 (59.53%) household contacts participated.

Conclusion: Newly designed “home-based intervention model” for active-case finding among household contacts of index pulmonary-TB case has been found an effective method for contact tracing. This intervention has adequate acceptance by the community and feasible for implementation under existing revised national tuberculosis control programme.

1. Introduction

Tuberculosis is caused by the *Mycobacterium tuberculosis*. Each year, TB affects 9 million people and kills almost 2 million people, primarily in resource limited settings [1]. In 2017, the estimated annual incidence of TB in India was 1.83 million cases [2]. Revised National Tuberculosis Control Programme (RNTCP) has achieved a lot in terms of reduction of the incidence and mortality due to tuberculosis in India. However, TB continues to remain a major public health problem in India.

All over the world, the household contacts of sputum smear positive pulmonary TB patient are considered as the *high-risk group of population* being infected with TB. “Risk Group” is any group of people in which the prevalence or incidence of TB is significantly higher than in the general population [3]. To prevent and control tuberculosis, screening of high-risk population is widely recommended. However, it is seldom practiced in developing countries because of lacking resources and absence of evidence based optimal programmatic approaches as per the local felt needs and practicability [3].

In 2012, WHO published: “*Recommendations for Investigating Contacts of Persons with Infectious Tuberculosis in Low- and Middle-Income Countries*” [4]. The main purpose of these recommendations was to assist *national and local public health tuberculosis control programmes* and implementing case finding among people exposed to infectious cases of TB. Even in this publication, there is an advisory for National TB Control Programme (like, *RNTCP in India*), that, ‘the *decisions* about whether to undertake *contact investigation* can be based on published estimates of the *prevalence or yield* of active TB among contacts’ [4].

The Central TB Division of Government of India has published “RNTCP Operational Research Agenda-2013” [5]. One of the topic in the agenda was as follows:

“*To design & evaluate interventions for active case finding in high risk groups (clinically and socially vulnerable population)*”

In this context, as per the need in Kashmir, we have designed the following interventional model (Fig. 1).

The rationale of designing such “home-based interventional model”

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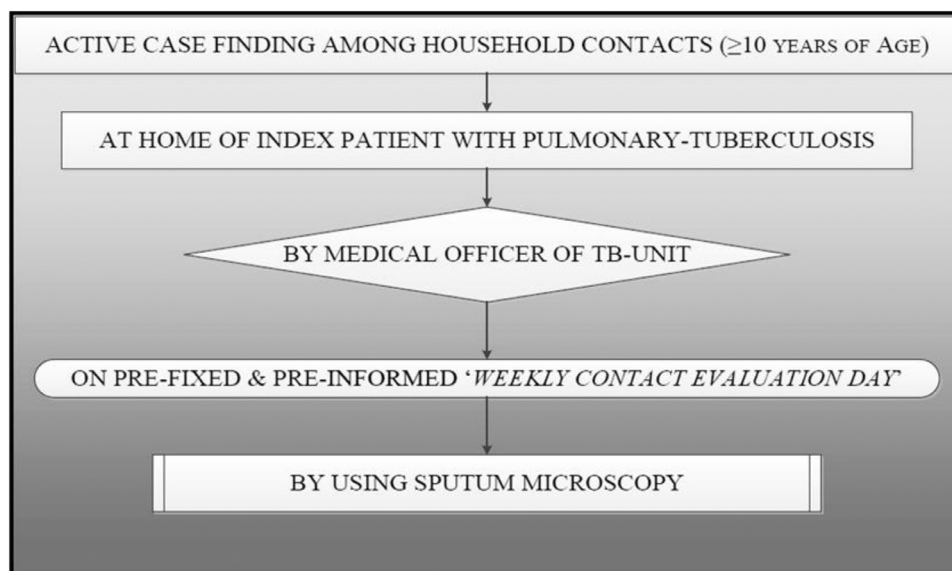


Fig. 1. Home-based Interventional Model for ACF among household of Index P-TB Case.

has been explained under following sub headings.

- a) **“Household contacts”**. They have been selected for intervention because they are close, most vulnerable and may be most receptive for the intervention.
- (a) **“Age of household contacts ≥ 10 years”**. In home setting it is not possible to collect quality sputum sample from less than 10 years of age. They usually swallow sputum rather than expectorate it [6]. So household contacts ≥ 10 years were included who were able to give valid history signs and symptoms of P-TB during verbal conversation with a doctor and who were able to provide a good quality spontaneous sputum specimen under home settings for testing in DMC.
- (b) **“At home of patient (index case)”**. Because we presumed that, to cover maximum possible number of household contacts of index case the service provider (Medical officer of TB Unit) should go for home visits of index case during his/her course of DOTS on fixed contact evaluation days. This presumption is based on facts that the uptake of hospital-based existing contact tracing strategy of RNTCP by the household contacts is not adequate which is adversely affecting contact tracing.
- (c) **“By Medical Officer of concerned TB Unit”**- In this model, it has been proposed that doctor (MO-TC of TB Unit) should take the job responsibility of visiting home of Index P-TB Case. Its importance is because of following facts:
 - > Doctor has been proved to be most acceptable out of all RNTCP staff by the household contacts with whom they can discuss about their signs and symptoms.
 - > MO-TC is the most trained person under RNTCP at TB-Unit level.
 - > MO-TC is most concerned person regarding the importance of enhancing TB case detection by utilising available logistics under RNTCP.
 - > Under existing RNTCP, the MO-TC is supposed to visit in the field under his jurisdiction during 7 tour days per month to monitor the programme activities. Out of the same 7 days, just 4 “pre-fixed weekly days” per month may be dedicated for household contact tracing without any major change and extra burden on the programme.

It is important to mention that in present study, due to financial implication and unapproved deviation from the programme, this responsibility of home visiting had been taken by the investigator himself.

- (d) **“On pre-fixed & pre-informed weekly contact evaluation day”**.

It has been proposed that any day of the week should be fixed for contact tracing among the household contacts of index case of pulmonary TB cases registered during the previous week. The information regarding the schedule of home visit should be conveyed to such cluster of contacts through the index case at the time of his/her registration on DOTS. Its importance in the interventional model is self-explanatory.

- (e) **“By using sputum microscopy”**. This is the method of choice for diagnosis. No other diagnostic tool for pulmonary-TB can work at home setting for contact screening better than the “Sputum specimen sampling” followed by its processing in nearest DMC.

1.1. Research question

Should the newly designed “home-based interventional model for active case finding” be promoted as alternative to existing approach of ‘passive case finding’ among household contacts of index P-TB case under RNTCP in Kashmir?

1.2. Hypothesis

The alternate hypothesis of this study is that, the home-based contact evaluation followed by sputum microscopy of symptomatic contacts is better alternative approach than the usual RNTCP practice of contact tracing.

1.3. Objectives

- a. To compare the effectiveness of “home-based intervention for active case finding” with yield of usual RNTCP practice of ‘passive case finding’ among household contacts of index pulmonary tuberculosis patients.
- b. To determine acceptance and feasibility of “home-based interventional model for active case finding” among household contacts of index P-TB cases under RNTCP.

2. Material and methods

For evaluation of the proposed model, quasi-randomized interventional study was designed. This study was conducted in two

predominantly-hilly districts in the northern state of Jammu & Kashmir in India. The state is divided into three geographically distinct 'Divisions' - Kashmir, Jammu and Ladakh. The state has implemented DOTS for the treatment of Tuberculosis in these areas since 2005. The annual total TB notification rate in the state during 2017 was 74/lakh/year, out of which 70% were cases of pulmonary TB.

Tuberculosis treatment under DOTS is provided through Tuberculosis Units (TUs) which cater to an average population of approximately 2.5 lakhs. At the time of this study, there were 21 TUs in Kashmir Division. We conveniently selected two TUs from Kashmir, Shopian and Uri - one each from the Southern and the Northern part of the valley. Both these TUs have a predominantly hilly population with higher TB notification rates as compared to other TUs. In each selected TB Unit, there were three designated microscopy centers (DMCs)

Weekly contact evaluation days were fixed for two TB Units. Study protocol was approved by the State RNTCP Operational research committee and the Ethical Committee of Government Medical College, Srinagar. Concerned staff were trained for their job responsibilities. Index cases were allotted to the interventional and control groups by "alternate assignment" method. "Alternate assignment" is a non-random ad hoc deterministic scheme for allocating intervention wherein one patient receives the intervention and the next patient in the list does not receive the intervention. We enlisted newly diagnosed TB patients from the TB Register maintained at the TU prospectively and assigned them to either receive the said intervention or not. The intervention for the first patient in the register was assigned randomly, thereafter alternating treatment assignment method was used. The details of who assigned the intervention and other job responsibility of staff are given in Table 1.

At the time of registration of index TB patients, senior treatment supervisor and MO-TC used to prepare complete list of household contacts with all necessary information. They were also responsible for alternate assignment of index cases into two groups.

In interventional group, investigator used to visit the home of index

case on fixed weekly contact evaluation day and investigate the household contacts using WHO recommended sample format [4]. Sputum specimen from the symptomatic contacts was collected and submitted to nearby DMC. Other sputum specimen used to be submitted to same DMC by any of any family member. First home visit used to be conducted within 1st week after registration of index case and follow up home visit used to be conducted at the completion of 6th month of treatment of the index case.

In Control group, it was just observed by the investigator from the contact register and laboratory register that how many household contact had attended the institution for their screening and sputum testing and out of them how many were detected as sputum smear positive P-TB cases as per the usual practice of contact tracing under RNTCP.

Index cases with their household contacts were enrolled from 1st Jan 2014 to 31st December 2014 and process of 6 monthly follow up was completed by 30th of June 2015. Sample size was not calculated apriori but based on data from years prior to 2014 we expected to recruit around 270 cases during the period.

Inclusion criteria was defined as bacteriologically confirmed index P-TB cases along with their household contacts (≥ 10 years of age), including transferred-in cases, registered in TB-Unit from 1st January 2014 to 31st December 2014.

Exclusion criteria was defined as those index P-TB Cases and their contacts, who were not the permanent residents of the geographical area of selected TB Unit.

Statistical analysis: The data was entered in Epi-Info version 7.1 [7] and analyzed using Epi-Info 7.1 and STATA 13 [8]. Independence between two categorical variables was tested using the Chi-square test. Unpaired *t*-test was used to test the difference between two independent sample means. Owing to clustering of contacts within a household, we used Generalized Estimating Equation with robust standard errors to model the relationship between case detection and intervention. Odds ratios along with the 95% Confidence intervals were reported. All

Table. 1
Fixed roles and responsibilities of staff involved in the study.

Activity	Staff
1. Registration of index cases in TB Register of selected TB Units.	STS & MO-TC
2. Maintenance of Contact Register.	
3. Alternate assignment of consecutive pulmonary-TB index cases to: (A) Controlled (Passive Case Finding) Group and (B) Interventional (Active-Case finding) Group	
A.-Controlled group of index P-TB cases along with their contacts:	
4. Initial counselling provided to index case and attendants and repetition of such awareness at various occasions of interaction.	STS & MO-TC
5. Line listing of index cases and contacts, using 'TB and Contacts Registers'.	Investigator
6. Sputum testing of those household contacts who complied with the advice of getting screened for TB.	L.T.
7. Any subject among 'household contacts' who diagnosed as 'Sputum smear-positive' for AFB was registered for DOTS.	STS & MO-TC
B.- Interventional group of index P-TB cases along with their contacts:	
8. Initial counselling provided to index case and information provided about initial home visit by the doctor (investigator).	STS & MO-TC
9. Monday for TU Shopian and Saturday for TU Uri were fixed as 'weekly contact evaluation days'.	HOD-Community Medicine
10. Line listing of index cases and contacts using 'TB Register and Contacts Register' and collection of required sputum containers from TU head quarter.	Investigator
B. 1- Initial home visit and baseline contact evaluation and sputum specimen testing:	
11.1. After line listing the Index cases and contact list, initial visit at home of index case for household contact evaluation for signs and symptoms of TB.	Investigator**
11.2. Spot 'sputum specimen collection' from TB Suspects and submission of same specimen to nearest DMC.	Investigator**
11.3. Information conveys to the family regarding day and date for follow up evaluation pf contacts after gape of 25 weeks.	Investigator**
11.4. Submission of "Morning sputum specimen" to same DMC.	Any family member**
11.5. Sputum testing (using RNTCP logistics) and result declaration.	L. T.
11.6. Any subject among 'household contacts' diagnosed as 'sputum smear-positive for AFB', was registered for DOTS.	STS & MO-TC
B. 2- Follow up home visit at 6th month and contact evaluation and sputum specimen testing:	
12.1. Second home visit for follow up contact screening at completion of 6th month of DOTS by index case.	Investigator**
12.2. Spot 'Sputum specimen collection', from TB Suspects, and its submission to nearest DMC.	Investigator**
12.3. Submission of "Morning sputum specimen" to same DMC.	Any family member**
12.4. Sputum testing (using RNTCP logistics) and result declaration.	L. T.
12.5. Any subject among 'household contacts' diagnosed as 'sputum smear-positive for AFB', was registered for DOTS.	STS & MO-TC

STS- Senior Treatment Supervisor, L.T.-Laboratory Technician, MO-TC- Medical officer Tuberculosis Control, DMC-Designated Microscopy Centre.

** Assisted by concerned DOTS provider.

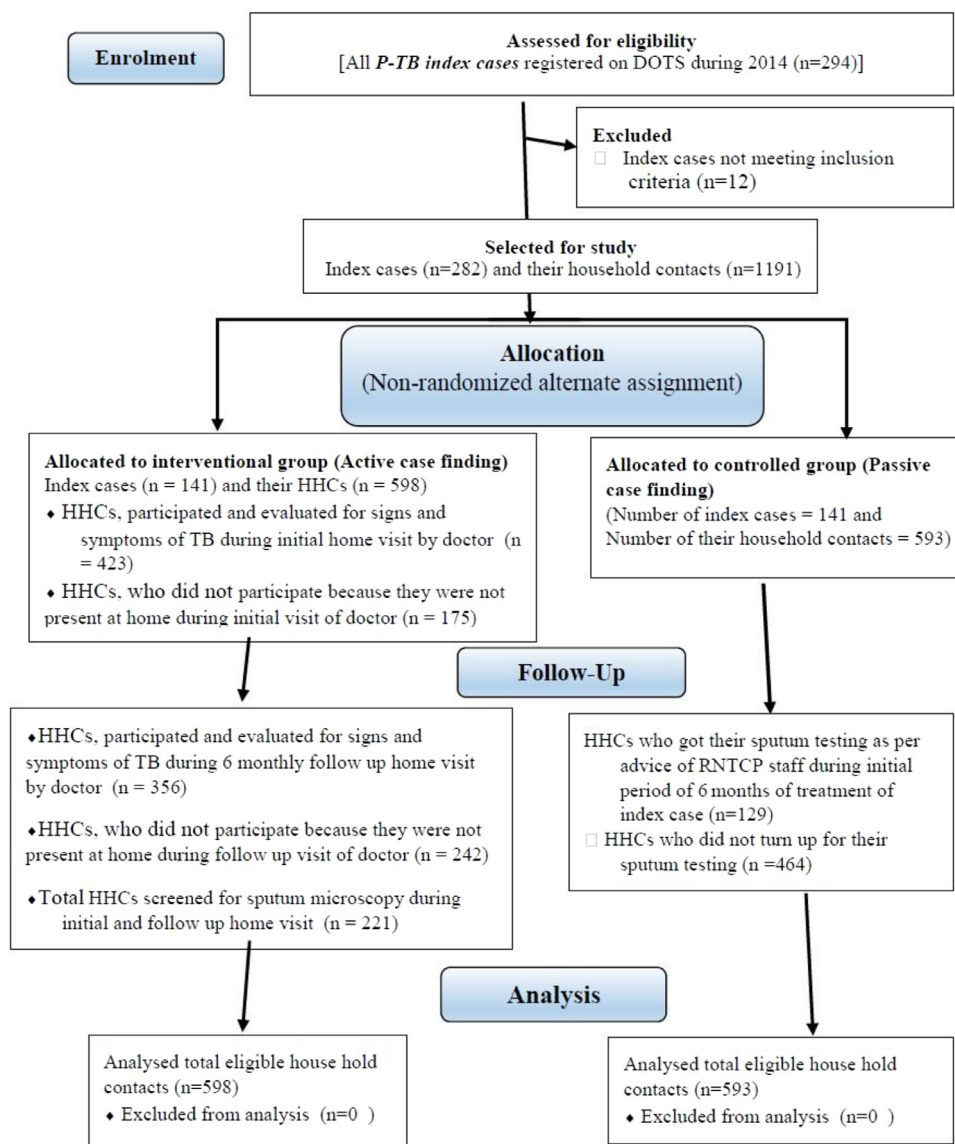


Fig. 2. Flow Diagram showing distribution of study subjects.

statistical tests were two-sided and p -value < 0.05 was considered statistically significant.

3. Results

Flow diagram in Fig. 2, shows details of distribution of study subjects.

Tables 2 and 3 show the study related characteristics of index cases and their household contacts in interventional and controlled groups. Even though alternate assignment was used for allocation of Index cases, there was *statistically no significant difference* regarding the distribution of study subjects in the Interventional and the Controlled groups in terms of their baseline characteristics.

Table 4 shows main outcome of present study that there is statistically significant difference between home-based intervention and usual RNTCP practice of household contact tracing in terms of detection of active pulmonary TB cases. So the alternate hypothesis is accepted.

Table 5 reveals that home-based intervention was more effective to enhance sputum testing of household contacts than the usual method for contact tracing under RNTCP.

Out of a total of 598 HHCs in the intervention group, 297 (49.7%) participated in TB evaluation at baseline as well as at 6-month follow-

up, 126 (21.1%) participated at baseline only and 59 (9.9%) participated at 6-month follow-up only. Overall 116 (19.4%) could not be evaluated for TB either at baseline or at 6-month follow-up

Table 6 reveals some common reasons for non-participation in intervention but no subject refused to give consent for evaluation and from providing sputum specimen for testing.

Fig. 3 shows that, in TB Unit Uri:

- The median number of households in interventional group, visited by investigator at baseline line was 1 per week, (with minimum of 0 and maximum of 3) and
- Had the controlled group been actively followed as per proposed intervention, the median number would have been 1 per week, (with minimum of 0 and maximum of 4).

Thus, the overall median number of households visited in TB Unit Uri would have been 2 per week (with minimum of 0 and maximum of 7). Almost similar observation was also found in TB Unit Shopian.

4. Discussion

The analysis of this study demonstrated detection of 3.5% co-

Table 2

Characteristics of index cases and their household contacts in interventional and controlled groups.

Characteristics	Index cases (N = 282)			Household Contacts (N = 1191)		
	Interventional group (N = 141)	Controlled group (N = 141)	Statistical Significance	Interventional group (N = 598)	Controlled group (N = 593)	Statistical Significance
Gender:						
Male	57 (40.4%)	73 (51.7%)	$\chi^2 = 3.65$, df = 1 $p = 0.055$	329 (55.0%)	301 (50.7%)	$\chi^2 = 2.16$, df = 1 $p = 0.141$
Female	84 (59.5%)	68 (48.2%)		269 (44.9%)	292 (49.2%)	
Mean age (Years)	42.0 (± 20.5)	42.0 (± 19.2)	Unpaired t-test $p = 0.990$	31.0 (± 16.4)	31.8 (± 16.5)	Unpaired t-test $p = 0.390$
Education:						
Illiterate	69 (48.9%)	58 (41.1%)	$\chi^2 = 3.94$, df = 3 $p = 0.267$ *grouped together for the purpose of analysis	157 (26.2%)	176 (29.6%)	$\chi^2 = 6.16$, df = 4 $p = 0.187$
Literate and till 5th standard	21 (14.8%)	19 (13.4%)		85 (14.2%)	67 (11.3%)	
6th to 10th standard	38 (26.9%)	41 (29.1%)		239 (39.9%)	216 (36.4%)	
11th to graduate	13 (9.2%)	22* (15.6%)		109 (18.2%)	128 (21.5%)	
Postgraduate	0 (0.0%)	1* (0.7%)		8 (1.3%)	6 (1.0%)	
Occupation:						
Agricultural cultivator	13 (9.2%)	19 (13.4%)	$\chi^2 = 5.37$, df = 7 $p = 0.614$	61 (10.2%)	45 (7.5%)	$\chi^2 = 10.29$, df = 7 $p = 0.172$
Business	5 (3.5%)	8 (5.6%)		33 (5.5%)	21 (3.5%)	
Govt./Private service	8 (5.6%)	13 (9.2%)		71 (11.8%)	74 (12.4%)	
Home maker	37 (26.2%)	26 (18.4%)		136 (22.7%)	163 (27.4%)	
Non- Agricultural & Skilled worker	13 (9.2%)	14 (9.9%)		48 (8.0%)	38 (6.4%)	
Student	26 (18.4%)	22 (15.6%)		174 (29.1%)	186 (31.3%)	
Unemployed	8 (5.6%)	9 (6.3%)		39 (6.5%)	30 (5.0%)	
Old age (> 60 Years)	31 (21.9%)	30 (21.2%)		36 (6.02%)	36 (6.0%)	

Table 3

Characteristics of index cases (N = 282) in interventional and controlled groups to whom their household contacts were exposed.

Characteristics	Interventional group (N = 141)	Controlled group (N = 141)	Statistical significance
Marital status:			
Married	73 (51.7%)	86 (60.9%)	$\chi^2 = 2.44$, df = 2 $p = 0.294$
Unmarried	44 (31.2%)	36 (25.5%)	
Widow (er)*	24 (17.0%)	18 (12.7%)	*grouped together for the purpose of analysis
Divorced*	0 (0.0%)	1 (0.7%)	
Category:			
General	111 (78.7%)	109 (77.3%)	$\chi^2 = 0.08$, df = 1 $p = 0.773$
Scheduled Tribe	30 (21.2%)	32 (22.7%)	
Patient Type:			
New	128 (90.7%)	127 (90.1%)	$\chi^2 = 0.04$, df = 1 $p = 0.839$
Recurrent	13 (9.2%)	14 (9.9%)	
Grading of sputum result:			
Scanty	18 (12.7%)	19 (13.4%)	$\chi^2 = 1.35$, df = 3 $p = 0.717$
1 +	71 (50.3%)	79 (56.0%)	
2 +	34 (24.1%)	29 (20.5%)	
3 +	18 (12.7%)	14 (9.9%)	

prevalent TB (those detected within two weeks following registration of index case) and 1.0% incident secondary TB (those detected during follow at 6th months later) among household contacts by application of newly designed home-based interventional model in intervention group. Therefore, total 4.5% household contacts were detected as active cases of TB till the initial 6 months after registration of the respective index TB cases. This study also showed that in non-intervention group of household contacts of index case, only 1.2% cases of active TB were detected during period of entire course of DOTS of the respective index

Table 4

Effectiveness of intervention in comparison to usual RNTCP practice (controlled group) in terms of case detection among household contacts.

P-TB Case detected	Interventional group (N = 598)	Controlled group (N = 593)	Odds ratio (95% CI)	p-value
Yes	27* (4.5%)	7** (1.2%)	3.97	0.001
No	571 (95.4%)	586 (98.8%)	(1.73–9.11)	

* Out of these, 21 (3.5%) cases were detected at base line [Co-prevalence of P-TB among HHCs (detected within maximum 2 weeks following registration of index case on DOTS) and 6 (1.04%) cases were detected at 6th monthly follow up [Incident secondary cases of P-TB among HHCs (detected at 6th month following registration of index case on DOTS)].

** Out of these, 5 cases were detected 'Early' (within 1 month after registration of Index case and 2 cases were detected 'Late' (any time from 2nd to 6th month after registration of Index case).

Table 5

Comparison between interventional and controlled groups in terms of proportion of household contacts whose sputum test was conducted to trace the active P-TB among them.

Sputum test conducted	Interventional group (N = 598)	Controlled group (N = 593)	Statistical significance
Yes	221* (36.4%)	129** (30.5%)	$\chi^2 = 33.16$, df = 1 $p < 0.001$
No	377 (39.6%)	464 (60.3%)	

* Out of these HHCs, 190 were tested at least once during base line evaluation or follow up evaluation and 31 HHCs were tested during 'follow up' out of total 59 participants who participated 1st time during follow up evaluation.

** Include those HHCs who were tested any time from date of registration of Index case on DOTS up to maximum 6th month of treatment of Index case.

Table 6

Primary reason* for absence of 'non participant household contacts' during "contact evaluation intervention".

Reasons	Non participants at 1st visit (N = 175)	Non participants at 2st visit (N = 219 ^a)
On current occupational work	77 (44.0%)	81 (36.9%)
In school/ other institutes of education	47 (26.8%)	72 (32.8%)
On Government Duty	31 (17.7%)	30 (13.6%)
Out of village for personal work	20 (11.4%)	36 (16.4%)

* Source of information: index case or head of the family.

^a 21 subjects detected as 'P-TB Cases at 1st visit were excluded for their eligibility to participate at 2nd visit and 2 HHCs who participated at 1st visit died before 2nd visit so excluded from total count.

cases by using the existing programmatic approach under RNTCP.

The analysis of this study also demonstrated the acceptance of intervention was satisfactory as 70.8% household contacts participated for screening at their respective homes whereas 30.5% household contacts participated for institutional screening in non-interventional group. In intervention group contact screening was done by the investigator whereas in non-interventional group screening was done by the medical officer posted at headquarter of TB Unit so there was no chance of contamination of intervention in control group.

The yield in our study of 3.5% co-prevalent TB cases among household contacts traced was lower than that observed by Singh et al. [9] in the peri-urban area of south Delhi where household contact tracing yielded 4.3% co-prevalent tuberculosis. We found of 1% case detection during follow up screening of household contacts at 6 month after registration of respective index case whereas in Delhi Singh et al. [9] found 2.6% incident secondary TB among household contacts during four follow up screenings six months apart for two years after registration of respective index cases.

According to the systematic review and meta-analysis study on contact investigation for tuberculosis conducted by Fox et al. [10] (commissioned for a WHO Expert Panel to develop global contact investigation guidelines), in 95 studies from low- and middle-income settings, the prevalence of TB among household contacts was 3.1% whereas the total 4.5% new TB Cases among household contacts were

detected in intervention group of present study. So the intervention in our present study was found to be effective to detect maximum active TB cases among household contacts.

The analysis of this study shows detection of 1.2% cases of active TB among household contacts TB by the existing approach under RNTCP for contact tracing is substantially lower than that the prevalence of 3.1% observed in the review and meta-analysis study by Fox et al [9]. Therefore, the existing RNTCP approach for contact tracing does not seems to be an effective approach so needs to be replaced by the active case finding approach.

In a review study in 2011, Fox et al. [11] concluded that there was insufficient data from randomized controlled trials or quasi-randomized controlled trials to evaluate the effect of active case finding for tuberculosis among contacts of TB patients. Present quasi randomized study has generated data which denote that intervention of active case finding is almost 3 times more effective than the passive approach of contact screening under existing RNTCP.

The yield of intervention at base line i.e. within two weeks following registration of index case much better than the follow up contact screening 6 months later. Therefore, in the interest of RNTCP, the best time for the application of suggested intervention model shall be during initial home visit and follow up active screening as done in present study can be ignored.

So far as the feasibility of intervention under routine setting is

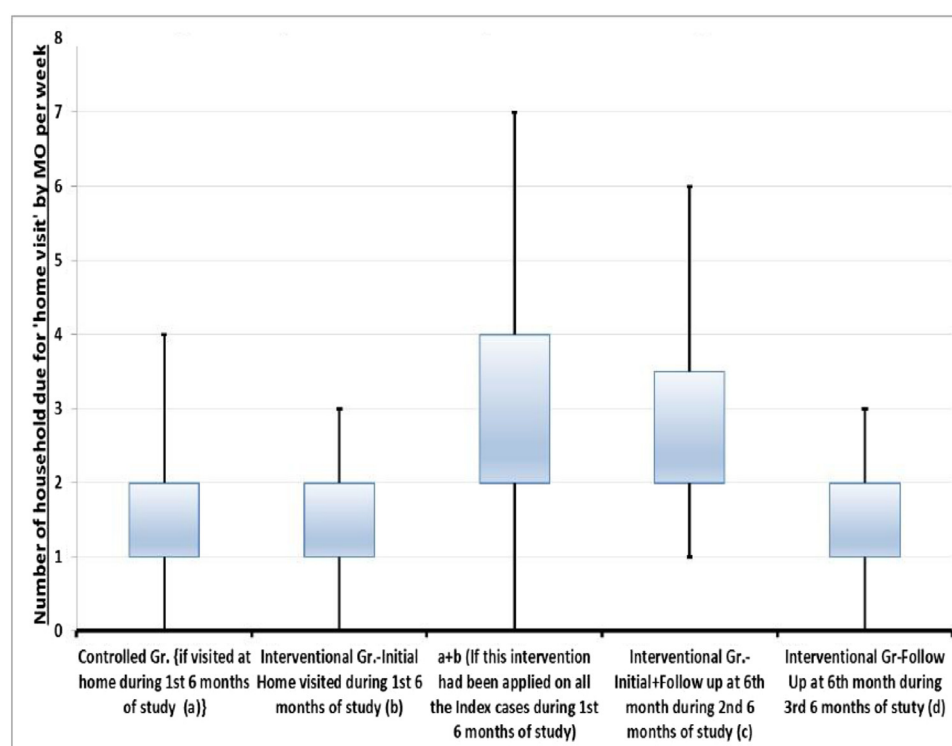


Fig. 3. Feasibility of home-based intervention in terms of work load of index cases per "weekly contact evaluation day" in TB Unit Uri during 2014.

concerned we found that we were able to work on it with minimum deviation from the existing RNTCP guidelines. As described in methodology of present study, except home visit by the investigator himself, all other work has been done by the human resource of RNTCP using available logistics available under the programme. So there will be no additional financial burden on programme by adopting the suggested model (intervention) for contact screening. Under existing programme MO-TU already visit in field for 7 days per month using hired vehicle to monitor RNTCP activities in his TU. Out of seven visits, four visits can be dedicated for fixed contact evaluation days in the field. In present study the weekly work load of index cases was manageable when their household contacts were screened on weekly fixed contact evaluation day.

The strength of present RNTCP operational research is the minimum deviation from the existing program while implementing the proposed intervention. The limitation of the present study is that due to time constrains only two TB units were selected for the study. It would have been better to test intervention at least one TU of each district of Kashmir.

5. Conclusion

On the basis of evidence obtained from present quasi-randomized trial, we conclude that:

- (a) The “home-based interventional model” is most effective for detecting co-prevalent active P-TB cases among household contacts of index P-TB case during initial home visit by the doctor. Second home visit at 6th month was not so effective, so can be omitted from the programme.
- (b) The suggested model has been found feasible for RNTCP to adopt in terms of utilization of existing human resource and logistics.
- (c) The acceptance of the suggested model in the community is satisfactory. A good number of household contacts participated for their screening at their home whereas under existing programme (control group) less number of contacts attended hospitals for screening.

Ethical clearance

The proposal of study was duly approved by the State RNTCP

Operational Research Committee and Institutional Ethical Committee of Government Medical College Srinagar.

Conflicts of interest

The authors have none to declare.

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